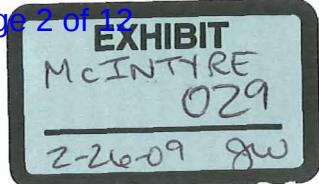


TAB 54



CONTRACT MANUFACTURING AGREEMENT

This agreement is entered into this 5th day of MAY 1993, by and between Boehringer Ingelheim Pharmaceuticals, Inc., 900 Ridgebury Road, Ridgefield, Connecticut 06877, (hereinafter referred to as "BOEHRINGER") and Roxane Laboratories, Inc., 1809 Wilson Road, Columbus, Ohio 43228, (hereinafter referred to as "ROXANE").

WHEREAS, BOEHRINGER is desirous of having ROXANE manufacture for it various pharmaceutical compounds in accordance with BOEHRINGER's specifications as hereinafter defined; and

WHEREAS, ROXANE possesses valuable facilities and know-how and employs personnel having skills relative to the preparation of pharmaceutical compounds and is willing to manufacture and sell such product(s) to BOEHRINGER in either bulk or finished package form in labeled put-ups.

NOW THEREFORE, in consideration of the premises and the undertakings of the parties hereinafter set forth the parties agree as follows:

1. DEFINITIONS

1.1 "PRODUCT" shall mean those pharmaceutical compound(s) designated in Attachment A, as well as such other pharmaceutical compounds subsequently added from time to time to Attachment A by mutual written consent. The parties shall identify with respect to each pharmaceutical compound in Attachment A how such product is to be supplied and labelled and/or packaged and which components shall be supplied by each party.

1.2 "SPECIFICATIONS" shall mean any and all specifications for manufacturing, packaging, labeling, and testing the PRODUCT which are identified in Attachment A, and for testing all ingredients and components necessary to produce those products, (including but not limited to the specifications as set forth in the BOEHRINGER's NDA and all supplements and amendments thereto). All SPECIFICATIONS and any changes agreed to by the parties from time to time shall be in writing, dated and signed by both parties.

1.3 "NDA" shall mean the New Drug Application(s) for the PRODUCT(s) approved by the FDA.

1.4 "FDA" shall mean the U.S. Food and Drug Administration.

1.5 "ACTIVE INGREDIENT" shall mean the active drug ingredient used by ROXANE in the manufacture of the PRODUCT(s).

1.6 "TRADEMARK" shall mean those trademarks which are used by BOEHRINGER in identifying the PRODUCT.

1.7 "TERM" shall mean the Initial Term and any Renewal Term(s) as hereinafter defined.

2. QUANTITY

2.1 ROXANE shall sell to BOEHRINGER and BOEHRINGER agrees to purchase from time to time from ROXANE, subject to the terms and conditions hereinafter set forth, quantities of the PRODUCT(s) during the TERM.

3. TERM OF AGREEMENT

3.1 This Agreement shall extend from the date first set forth above and shall continue for a ten (10) year Initial Term. Thereafter, the Agreement shall be automatically renewed for successive periods of five (5) years each (Renewal Term(s)), beyond the Initial Term, unless or until written notice of termination is given by either party to the other not less than two hundred forty (240) days prior to the end of the Initial Term or any Renewal Term(s) or unless sooner terminated or modified pursuant to one of the remaining provisions of this Agreement.

3.2 This Agreement may be terminated by written notice by either party in the event that the other has defaulted in any manner and shall have failed to remedy such default within sixty (60) days after notice thereof from the other party.

3.3 This Agreement may be terminated on not less than twelve (12) months prior written notice by either party in the event control, defined as 50% or more equity ownership, of either party changes.

3.4 Upon the expiry, termination or cancellation of this Agreement for any reason, by either party, BOEHRINGER shall purchase from ROXANE all remaining PRODUCT, work-in-process, ingredients, and components which are used to manufacture the PRODUCT, which ROXANE would not have purchased except for its manufacture of the PRODUCT for BOEHRINGER, at the price(s) then in effect, except if such termination or cancellation is as the result of breach by ROXANE. The foregoing inventories shall be shipped to BOEHRINGER at BOEHRINGER's expense or destroyed.

3.5 Termination of this Agreement shall not relieve either party from any liabilities or obligations which may have accrued prior to the date of termination, including the obligation to pay for PRODUCT delivered to BOEHRINGER or the mutual obligations of confidentiality and indemnity.

4. PERFORMANCE

4.1 BOEHRINGER and ROXANE shall share technical information and associated services to enable BOEHRINGER to file a complete NDA and ROXANE to produce the PRODUCT, in conformity with BOEHRINGER's NDA(s) and the SPECIFICATIONS.

4.2 ROXANE shall test and release the PRODUCT prior to shipment to BOEHRINGER. BOEHRINGER shall test the PRODUCT after receipt as BOEHRINGER deems appropriate. If, within thirty (30) days after receipt of the PRODUCT by BOEHRINGER at BOEHRINGER's facility, BOEHRINGER notifies ROXANE in writing that the PRODUCT does not meet the SPECIFICATIONS, ROXANE shall with reasonable promptness replace all such non-conforming PRODUCT, F.O.B. BOEHRINGER's facility, with PRODUCT meeting the SPECIFICATIONS. Such notification by BOEHRINGER to ROXANE shall indicate the Specification claimed to be unmet and the test procedure used in making this conclusion. Non-conforming PRODUCT shall, upon mutual agreement by ROXANE and BOEHRINGER and at ROXANE's sole expense, either (i) be returned to ROXANE for rework or destruction within a reasonable period of time or (ii) be destroyed by BOEHRINGER. A credit shall be issued by ROXANE within forty-five (45) days of agreement that the PRODUCT is non-conforming or such determination is made by an independent testing laboratory.

4.3 If ROXANE and BOEHRINGER do not agree on whether PRODUCT meets SPECIFICATIONS, the matter will be submitted for testing to an independent testing laboratory acceptable to both parties. The determination of such independent laboratory will be binding on both parties. The cost of the independent testing laboratory shall be borne by the party whose testing results were in error.

4.4 Either of the parties shall have the right to request changes to the SPECIFICATIONS. Recommendations to change any SPECIFICATIONS shall be in writing. No change in the SPECIFICATIONS shall be implemented by either party, whether requested by either of the parties or requested or required by any governmental agency, until the parties have agreed in writing to such change.

4.5 Inventories of PRODUCT, ingredients, packaging and labeling components, in-process work and any finished goods which cannot be used by ROXANE as the result of a change in the SPECIFICATIONS shall be identified by ROXANE and purchased by BOEHRINGER from ROXANE at ROXANE's cost, provided ROXANE has not maintained inventories which are inconsistent with BOEHRINGER's planned purchases as set forth in Paragraph 6.4

4.6 ROXANE shall promptly notify BOEHRINGER of any problems or unusual production situations which have the potential to adversely affect production of the PRODUCT, or its timely delivery to BOEHRINGER.

5. ADVERSE DRUG AND PRODUCT COMPLAINT REPORTS

5.1 BOEHRINGER shall be responsible for reporting to the FDA, if required, any adverse drug experiences associated with the PRODUCT.

5.2 If ROXANE receives any reports of adverse drug experience associated with the PRODUCT, or other complaints about the PRODUCT, ROXANE shall provide BOEHRINGER with a copy of such report(s) within five (5) business days of the receipt of same. BOEHRINGER shall be responsible for investigating such reports, for reporting them to the FDA, or other governmental agency, if necessary, and for corresponding with the complainant. ROXANE shall provide reasonable assistance to help BOEHRINGER investigate adverse events or product complaints involving the manufacture of the PRODUCT.

6. ORDER PROCEDURE

6.1 BOEHRINGER agrees to purchase the PRODUCT in production batch quantities or multiples thereof.

6.2 PRODUCT shall be ordered on BOEHRINGER's standard purchase order forms. The terms and conditions contained thereon, to the extent they are inconsistent or in conflict with the provisions of this Agreement or impose additional obligations on ROXANE, are considered to have no effect.

6.3 BOEHRINGER's purchase order shall set forth the quantities of PRODUCT and the desired delivery date.

6.4 A twelve (12) month forecast of anticipated purchases of the PRODUCT, including estimated delivery dates, shall be submitted to ROXANE every month during the term of this Agreement. The first six (6) months of each forecast shall be considered a firm order for purchasing components and raw materials, however, ROXANE is not authorized to institute production until it receives BOEHRINGER's purchase order. BOEHRINGER's purchase orders will be issued prior to the desired delivery date by at least sixty-five (65) days for each batch required to produce the quantity of PRODUCT on the order. ROXANE will exercise reasonable efforts to ship the quantities ordered in the time frame specified on BOEHRINGER's Purchase Orders, even if quantities are in excess of the forecast. BOEHRINGER will in turn, exercise reasonable efforts to level load production requirements.

6.5 In addition to the production forecasting obligations set forth in Paragraph 6.4, upon the execution of this Agreement, and on every anniversary date thereafter during the term of this Agreement, BOEHRINGER shall provide ROXANE with a non-binding three (3) year projection of anticipated future purchases of the PRODUCT by year, for the sole purpose of permitting ROXANE to plan future purchases of capital equipment that may be required to manufacture the PRODUCT.

7. PAYMENTS

7.1 ROXANE agrees to sell and BOEHRINGER agrees to purchase the PRODUCT at the prices set forth in Attachment B, attached hereto and made a part hereof. All PRODUCT shall be shipped F.O.B. Columbus, Ohio according to the BOEHRINGER purchasing order instructions and invoiced at the time ROXANE releases and ships the Product. Payment terms are net 30 days.

7.2 The parties agree that the purchase prices set forth in Attachment B shall remain in effect through December 31, 1993. Thereafter, the prices shall be negotiated between the parties annually to reflect any increased costs incurred by ROXANE in purchasing the ingredients and/or components of the PRODUCT, and any increase in cost due to an increase in labor and/or overhead.

8. LABELS, LABELING

8.1 BOEHRINGER shall specify the tradedress and trademarks which will appear on the label, and package inserts identifying the PRODUCT. BOEHRINGER will supply ROXANE with finished, camera ready, mechanical art for all labeling.

9. TRADEMARKS

9.1 The TRADEMARK is the sole and exclusive property of BOEHRINGER.

9.2 BOEHRINGER agrees that the TRADEMARK or marks and tradedress selected by it shall not be confusingly similar to any trademark or tradedress used by ROXANE.

9.3 ROXANE recognizes and agrees that the TRADEMARKS selected by BOEHRINGER for use in connection with the PRODUCT and the tradedress, labels, or labeling or designs used in connection with the PRODUCT are the property of BOEHRINGER and that it will have no right in or to the said marks.

10. CONFIDENTIALITY

10.1 Each party agrees that all data and information received by it pursuant to this Agreement shall be retained in confidence. Each party shall bind the recipients of such information to the confidentiality terms contained herein. This commitment shall not apply if the information is or becomes public knowledge without the fault of the recipient party; or where the information is properly provided to a party by an independent third party; or where a party can show that the information was already in its possession at the time of receipt from the other party; or where the information is required or subpoenaed by any governmental agency, body or Court who shall be informed of the confidential nature of such information. The obligations under this paragraph shall survive the TERM.

11. WARRANTIES

11.1 ROXANE represents and warrants that the PRODUCT, packaging components, and labeling components shall conform to the SPECIFICATIONS and that the PRODUCT shall be manufactured in accordance with the Current Good Manufacturing Practice Regulations of the U.S. Food and Drug Administration. ROXANE warrants that the PRODUCT shall not be a product which is adulterated or misbranded within the meaning of section 505 of the Federal Food, Drug and Cosmetic Act, as amended, and the regulations issued thereunder or within the meaning of any state or local law, the adulteration and misbranding provisions of which are similar to the Federal Act or is a product which may not, under the provisions of any law or regulations, be introduced into interstate commerce. Excluded from the above representations and warranties are any failures of the PRODUCT due to defects in the SPECIFICATIONS, the PRODUCT's NDA, any ingredients and/or components provided to ROXANE by BOEHRINGER.

11.2 BOEHRINGER represents and warrants that it has no knowledge of any third party patent or trademark rights that would be infringed by ROXANE's activities under this Agreement.

11.3 BOEHRINGER warrants that all label copy, artwork and all information supplied to ROXANE shall not be false or misleading in any particular and shall be in compliance with applicable FDA regulations and BOEHRINGER's NDA.

12. INDEMNITY/INSURANCE/RECALLS

12.1 BOEHRINGER shall defend, indemnify, protect, and save ROXANE harmless from all claims, demands, suits, or proceedings for damages, costs (including reasonable attorney's fees), expenses and losses which arise (1) from any claim or charge by a third party for trademark or patent infringement, or unfair competition arising out of or in connection with the promotion, marketing, distribution or sale of the PRODUCT by BOEHRINGER or of the use and manufacture of the PRODUCT in conformity with the SPECIFICATIONS or (2) as the result of any breach of this Agreement by BOEHRINGER or (3) out of any claim for product liability arising from the use of the PRODUCT; provided, however that ROXANE will not be indemnified for any claims arising solely as the result of the manufacture of the PRODUCT which fails to conform to the SPECIFICATIONS or is in violation of the warranties set forth in Article 11.

ROXANE will defend, indemnify, protect, and save BOEHRINGER harmless from all claims, demands, suits or proceedings for damages and costs (including reasonable attorney's fees), expenses and losses which arise solely as the result of ROXANE's failure to provide the PRODUCT in conformity with the SPECIFICATIONS or in violation of the warranties set forth in Article 11.

12.2 The party claiming indemnification shall, immediately upon receipt of notice of any such claim or suit, notify the other party, fully cooperate with the other party in defense of the claim or suit, or permit the other party's attorney(s) to handle and control such claims or suits, except that the party claiming indemnification shall be entitled to select counsel, participate therein and assume the defense thereof at its own expense but in any event, shall keep such other party informed of the progress of any such claims or suits including notification of final disposition.

12.3 Effective throughout the TERM and thereafter, for a period of not less than four (4) years, the parties shall each carry and maintain in full force and effect insurance, insuring themselves for comprehensive general liability, including product liability.

12.4 Any expense incurred by ROXANE from an injunction, recall, stop sale or governmental action or directive, shall be the responsibility of BOEHRINGER provided such actions, recall and/or stop sale does not arise from a breach of the Agreement by ROXANE.

12.5 ROXANE shall reimburse BOEHRINGER for the expense of a recall, stop sale or governmental action or directive, resulting from a breach of this Agreement by ROXANE, to the extent of providing a quantity of PRODUCT to BOEHRINGER sufficient to replace that quantity of PRODUCT that was recalled or was the subject of such stop sale, governmental action or directive as well as for necessary and proven out of pocket expenses for an amount not to exceed the purchase price for the batch(es) of PRODUCT recalled. Such out of pocket expenses shall be reimbursed by ROXANE by the issuance of a credit which shall only be applied against future purchases of the PRODUCT.

13. PRODUCTION FACILITY INSPECTION

13.1 BOEHRINGER shall have the right, at reasonable intervals and on reasonable prior notice during normal business hours, to inspect those sections of ROXANE'S manufacturing, laboratory, packaging and warehousing facilities used in the manufacture, packaging, storage, testing, shipping or receiving of the PRODUCT or its components.

13.2 In the event that ROXANE's facilities are the subject of an inspection by any duly authorized agency of the federal, state, local or any foreign government and the inspection is specific for the PRODUCT, ROXANE shall notify BOEHRINGER of such inspection and provide to BOEHRINGER a summary of findings as directly relates to the manufacture of the PRODUCT.

14. GENERAL TERMS

14.1 This Agreement shall be governed and construed in accordance with the laws of the State of Ohio and any and all disputes arising under or concerning this Agreement shall be before the Courts of the State of Ohio.

14.2 Any notice, required or permitted to be given under this Agreement, shall be in writing, postpaid, by registered or certified mail, addressed to the party to be notified at its address stated below:

If to ROXANE
President or his designee
Roxane Laboratories, Inc.
P.O. Box 16532
Columbus, Ohio 43216

If to BOEHRINGER
President or his designee
Boehringer Ingelheim
Pharmaceuticals, Inc.
900 Ridgebury Road
Ridgefield, CT 06877

14.3 No liability shall result from delay in performance in whole or in part if performance as agreed has been made impracticable by compliance in good faith with any applicable foreign or domestic governmental regulations or order whether or not it later proves to be invalid, or by the occurrence of a contingency the non-occurrence of which was a basic assumption on which this Agreement was made, including, but not limited to, acts of God, fire, flood, accident, riot, war, sabotage, strike, labor trouble or shortage, embargo or ROXANE's inability to obtain at prices and on terms deemed by it to be practicable, any required raw material, component, equipment, labor or transportation. If any such circumstances affect only a part of ROXANE's capacity to perform, ROXANE shall have the right to allocate production and deliveries among all of its customers and its own requirements. Quantities affected by this paragraph may, at the option of either party, be eliminated from the Agreement without liability, but the Agreement shall remain otherwise unaffected.

14.4 The failure of either party to insist on strict performance of any provision or to take advantage of any right hereunder shall not be construed as a waiver or any subsequent performance of such provision or right.

14.5 The headings and captions contained herein are for reference only and shall not constitute a substantive part of this Agreement.

14.6 The parties are and will remain at all times independent contractors, and no agency or employment relationship exists between them.

14.7 This Agreement may not be assigned by either party without the written consent of the other (which consent shall not be unreasonably withheld) except to a subsidiary or in the case of

sale or transfer of all or substantially all of its business by way of acquisition, consolidation or merger.

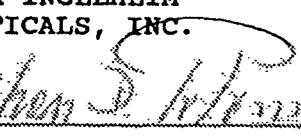
Notwithstanding the foregoing, this Agreement shall be binding upon the respective successors and assigns of either party hereto.

14.8 If any provisions of this Agreement are held invalid or unenforceable, unless the invalidity or unenforceability substantially frustrates the underlying intent and sense of the remainder of the Agreement, such invalidity and unenforceability shall not affect the validity or enforceability of any other provisions of the Agreement except those where the invalidated or unenforceable provisions comprise an integral part of, or are otherwise clearly inseparable from, the intent and sense of the Agreement. In the event any provision is held invalid or unenforceable, the parties will attempt to agree upon a valid and enforceable provision which shall be a reasonable substitute for such invalid or unenforceable provision in light of the intent of this Agreement and upon so agreeing, shall incorporate such substitute provision in this Agreement.

14.9 This document contains the entire Agreement between the parties pertaining to its subject matters and shall not be altered or modified, except in a writing signed by the party to be bound by such alteration or modification.

IN WITNESS WHEREOF, the parties hereto have caused this Agreement to be executed by their duly authorized representatives as of the date and year first written above.

BOEHRINGER INGELHEIM
PHARMACEUTICALS, INC.

BY: 

DATE: 3/29/93

ROXANE LABORATORIES, INC.

BY: 

DATE: 5/15/93

CONTRACT MANUFACTURING AGREEMENT
between BOEHRINGER and ROXANE

ATTACHMENT A

PRODUCTS manufactured by ROXANE for BOEHRINGER:

Alupent Solution 0.4%, 25 labeled unit dose vials per packer with one insert, 48 tamper taped packers per shipper.

Alupent Solution 0.6%, 25 labeled unit dose vials per packer with one insert, 48 tamper taped packers per shipper.

Atrovent Solution 0.02%, 25 unit dose vials in labeled foil pouch, one pouch and one insert per packer, 48 packers per shipper.

Atrovent Solution 0.02%, 2 unit dose vials in labeled foil pouch, 6 pouches per packer, 12 packers and one insert per shipper.

The Parties acknowledge that ROXANE is to supply all materials and components for the above noted PRODUCTS, in accordance with the current SPECIFICATIONS which are in the possession of ROXANE.

April 29, 1993

ATTACHMENT B

**1993 PRICES FOR ALUPENT UNIT DOSE SOLUTION
AND ATROVENT UNIT DOSE SOLUTION**

PRODUCT NAME	DESIGNATION	UNIT OF MEASURE	PRICE PER UNIT OF MEASURE
ALUPENT INHALANT 0.4% UNIT DOSE SOLUTION	COMMERCIAL PACK	25 VIALS	\$7.25
ALUPENT INHALANT 0.6% UNIT DOSE SOLUTION	COMMERCIAL PACK	25 VIALS	\$7.50
ATROVENT INHALATION 0.02% UNIT DOSE SOLUTION	COMMERCIAL PACK	25 VIALS	\$10.75
ATROVENT INHALATION 0.02% UNIT DOSE SOLUTION	SAMPLE PACK	2 VIALS	\$0.90